

Appl. No. : 09/829,631
Filed : April 10, 2001

IN THE SPECIFICATION:

On page 1, after line 1, please delete the paragraph claiming the benefit of an earlier filing date and cross-references to other applications under 37 CFR 1.78(a)(2) and add the following paragraph as its substitute:

Related Applications

This application is a continuation of U.S. Pat. Appl. No. 08/428,242, filed September 18, 1995, which is the U.S. National Phase under 35 USC § 371 of International Application No. PCT/US93/10296, filed October 26, 1993, which is a continuation-in-part and claims the benefit of priority of U.S. Appl. No. 07/970,338, filed October 26, 1992.

REMARKS

Applicant wishes to thank Examiner Marianne Allen for the courtesy extended to their representative, Nancy Vensko, and colleagues, Marina Gordey and Eric Ives, on November 15, 2002. The Interview Summary Form PTOL-413 summarizes the discussions held at the personal interview. The present response to the outstanding Office Action includes the substance of the Examiner Interview.

A. Disposition Of Claims

The invention is related to the serotonin receptor protein St-B17. Under Specification at 6:29-30 and Specification at 6:36 – 7:6, the serotonin receptor protein St-B17 exhibits a distinct pharmacological profile not previously described. The unique pharmacology together with the relatively low level of homology (<50%) of St-B17 with previously cloned 5-HT receptor subtypes indicates that this receptor does not belong to any of the previously defined subcategories of 5-HT receptors. Thus, St-B17

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represents a previously unknown and uncharacterized receptor. By this amendment, Applicant has (1) canceled original Claims 1-37 (copy of International Preliminary Examination Report for International Appl. No. PCT/US93/10296, with Claims 1-37 made under PCT Article 34, attached), which were incorporated by reference under the transmittal sheet of this application, 09/829,631, filed April 10, 2001 (as NIH047.1CP1C1); (2) renumbered added Claims 1-16 as Claims 38-53 and then canceled renumbered Claims 38-53; and (3) added new Claims 54-65. The reason is to protect claims decided by the European Patent Office to be allowable, and thus, the purpose is for reasons unrelated to patentability. A copy of the corresponding European Patent No. EP 0 668 912 B1 is attached. Claims 54-65 are presented for examination. All claims fall within the restriction group elected in response to the previous restriction requirement. Support for the amendment is found throughout the specification, for example, as set forth below with reference to International Application. No. PCT/US93/10296 (attached). No new matter is added, neither a deposit nor a new sequence listing. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Claim	Support in International Application. No. PCT/US93/10296 (attached)
54	Original Claim 7, Original Claim 10, SEQ ID NO:7, SEQ ID NO:12, Example 9 at 22:30 – 23:6, SEQ ID NO: 8, SEQ ID NO:13, Table 1, Specification at 6:29-30, Specification at 6:36 – 7:6, Specification at 12:22-24, Specification at 19:1-7, and Specification at 21:3-11. Additionally, under Specification at 6:29-30 and 6:36 – 7:6, Example 9 contemplates these affinity binding characteristics for the human homolog; and Kohen et al., J. Neurochem. 66:47 (1996) (of record) confirms these affinity binding characteristics for the human homolog at Table 2.
55	SEQ ID NO:7
56	SEQ ID NO:12

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57	Example 9 at 22:30 – 23:6
58	SEQ ID NO: 8 and SEQ ID NO:13
59	Original Claim 7
60	Original Claim 20
61	Original Claim 24
62	Original Claim 13
63	Original Claim 15
64	Original Claim 16
65	Original Claim 1

B. Status of Application as Continuation

The status of this application is a continuation. As described above, Applicant has (1) canceled original Claims 1-37 (copy of International Preliminary Examination Report for International Appl. No. PCT/US93/10296, with Claims 1-37 made under PCT Article 34, attached), which were incorporated by reference under the transmittal sheet of this application, 09/829,631, filed April 10, 2001 (as NIH047.1CP1C1); (2) renumbered added Claims 1-16 as Claims 38-53 and then canceled renumbered Claims 38-53; and (3) added new Claims 54-65. Claims 54-65 are presented for examination. Support for the amendment is found throughout the specification, for example, as set forth above with reference to International Application. No. PCT/US93/10296 (attached). Additionally, by this amendment, the specification claims the benefit of an earlier filing date and cross-references to other applications under 37 CFR 1.78(a)(2). No new matter is added, neither a deposit nor a new sequence listing. A result of the status of this application as a continuation is that no supplemental oath or declaration is required.

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C. Sibley et al. (WO94/10310) As Post-Filing Date Art

Another result of the status of this application as a continuation is that Applicant is entitled to the benefit of October 26, 1992. Sibley et al. (WO94/10310) was published May 11, 1994. Therefore, Sibley et al. (WO94/10310) constitutes post-filing date art, not pre-filing date art, and as such cannot anticipate the invention.

Turning to Ruat et al., Biochem. Biophys. Res. Commun. 193:268 (May 1993) (of record), this reference does not constitute prior art. MPEP 715.03 states, "Where the only pertinent disclosure in the reference or activity is a single species of the claimed genus, the applicant can overcome the rejection directly under 37 CFR 1.131 by showing prior possession of the species disclosed in the reference or activity." Here, Ruat et al. described a rat serotonin receptor, a single species of Applicant's claimed genus. Thus, Applicant can overcome a rejection by filing a Rule 131 affidavit to show prior possession of the species disclosed in Ruat et al. Yet Applicant had already filed their priority application on October 26, 1992, describing Ruat et al.'s rat serotonin receptor showing prior possession of the species disclosed in Ruat et al. Thus, under the MPEP, Ruat et al. does not constitute patentability-defeating prior art.

As for WO91/17174, USP 5,472,866 to Gerald et al., and USP 4,985,352 to Julius et al. (all listed in the IDS of record), none of these references describes nor suggests the serotonin receptor protein St-B17 defined in the present claims. Under Specification at 6:29-30 and Specification at 6:36 – 7:6, the serotonin receptor protein St-B17 exhibits a distinct pharmacological profile not previously described. The unique pharmacology together with the relatively low level of homology (<50%) of St-B17 with previously cloned 5-HT receptor subtypes indicates that this receptor does not belong to any of the previously defined subcategories of 5-HT receptors. Thus, St-B17 represents a previously unknown and uncharacterized receptor. Accordingly, these references fall outside the scope of the present claims.

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CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12/10/02

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CLEAN VERSION OF ENTIRE SET OF PENDING CLAIMS

54. An isolated nucleotide sequence encoding a serotonin receptor protein St-B17, said protein exhibiting high affinity binding for clozapine, loxapine and amoxipine as determined by having a K_i value under 100 nM, said nucleotide sequence being selected from:
- (a) a nucleotide sequence comprising SEQ ID NO:7;
 - (b) a nucleotide sequence comprising SEQ ID NO:12;
 - (c) a nucleotide sequence hybridizing under moderate stringency conditions at 6XSSC and 55°C, pH7, to a 1192 bp XmaI-BstXI or a 655 bp BamHI-EagI fragment from SEQ ID NO:7; or
 - (d) a nucleotide sequence encoding a protein having the amino acid sequence shown by SEQ ID NO:8 or SEQ ID NO:13.
55. The nucleotide sequence according to Claim 54, wherein said nucleotide sequence is selected from (a).
56. The nucleotide sequence according to Claim 54, wherein said nucleotide sequence is selected from (b).
57. The nucleotide sequence according to Claim 54, wherein said nucleotide sequence is selected from (c).
58. The nucleotide sequence according to Claim 54, wherein said nucleotide sequence is selected from (d).
59. A recombinant construct comprising the nucleotide sequence according to Claim 54, operably linked to a heterologous promoter.
60. The recombinant construct according to Claim 58, which is an expression vector.
61. The recombinant construct according to Claim 60, which is a eukaryotic expression vector.

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62. A mammalian cell line comprising the nucleotide sequence of Claim 54, said mammalian cell line expressing St-B17 serotonin receptor.
63. The cell line of Claim 62, wherein said cells are derived from a human.
64. The cell line of Claim 63, wherein said cells are HEK 293.
65. An isolated protein encoded by the nucleotide sequence of any of Claims 54-58.

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